

5. 510 (k) Summary

JUL 13 2012

Owner's Name:	Micropoint Technologies Pte Ltd
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Name of Contact Person:	Mr Chee Yen <u>Lim</u>
Date:	31 August 2011
Trade/Proprietary Name:	PLANCET
Common Name:	Blood Lancet
Class:	Class I (Exempt)
Classification Name:	Lancet, Blood (Product Code: FMK, Regulation No. 878.4800)
Legally Marketed Predicate Device	CLEANLET, CLEANLET XL & KIDS (K931827)
Description of the Device:	<p>The PLANCET blood lancet is a needle device to be loaded in a lancing device for pricking a patient's finger or palm to draw a micro-litre sample of whole blood to perform in-vitro diagnostic (IVD) blood tests. Most point-of-care (POC) IVD devices rely on micro-sample quantities of capillary whole blood to carry out the analysis on the blood content, which may include glucose concentration, cholesterol level, and the absence or presence of antigens and antibodies. Blood lancets are commonly used by end users who regularly perform the IVD tests at home, such a glucose monitoring tests.</p> <p>The predicate device normally has a stainless steel needle encapsulated by a plastic material to form a body and a cap. This encapsulation ensures the needle integrity and sterility till point of use. To use the device, the user will twist off the cap to expose the needle and load the device into a spring operated lancing device. The device will be actuated and retracted rapidly to penetrate the skin and create a small wound on the skin for getting some capillary whole blood. More volume of blood can be obtained by compressing or massaging (milking) the lanced site.</p> <p>On the other hand, the PLANCET has exactly the same design, i.e. a needle that is encapsulated by a plastic material that forms a body and a cap. This plastic encapsulation ensures the needle's</p>

	<p>integrity and sterility till point of use. However, in this case, the needle is also made of a plastic material. The procedure to use PLANCET is to pull off the cap and to load PLANCET into a spring operated lancing device. Once triggered, the PLANCET will be actuated and retracted rapidly to penetrate the skin and create a small wound for getting some capillary whole blood.</p>
Indications for Use/ Intended Use:	<p>The PLANCET blood lancet is a puncture device to obtain micro-litre capillary whole blood samples from finger tips or palm or alternate body sites. The PLANCET blood lancet is normally loaded in a spring-operated lancing device for rapid puncture of skin.</p>
Technological Characteristics of the Device	<p><u>Manufacturing aspects:</u></p> <p>The manufacturing process of the predicate device comprises stainless steel needle fabrication and plastic over-moulding. Stainless steel wires are cut into small lengths and ground sharp, after which they are de-burred and polished by an electro-chemical process. Optionally, the ground needles can be coated with a layer of silicone lubricant. Finally, the ground needles are fed into an injection moulding machine to over-mould plastic materials e.g. polyethylene (PE) forming a body and a cap, encapsulating the ground needles. Terminal sterilization process is performed to ensure sterility of entire products. Note that the high temperature of the moulding process may sterilize the needles and keep the sterile condition intact until the cap is twisted off.</p> <p>The manufacturing of PLANCET comprises injection moulding of plastic needles and plastic over-moulding using polyethylene PE (exactly the same process as involved in the predicate device). Instead of cutting wire into small lengths, grinding and polishing needles..., one single injection moulding process is used to fabricate the plastic needles. The plastic material is a high performance and bio-compatible plastic material.</p> <p><u>Design & Functionality aspects:</u></p> <p>The predicate device comprises a stainless steel needle encapsulated with a plastic body and a cap, the cap is twisted off to expose the needle for use. The predicate device is normally loaded into a spring-operated lancing device, which rapidly penetrates the skin to obtain micro-litre sample of capillary whole blood.</p> <p>The PLANCET has exactly the same design and functionality as compared with the predicate device. One minute difference will be instead of twisting off the cap to expose the needle, the</p>

	<p>PLANCET requires the end user to pull off the cap, which is a simpler procedure.</p> <p><u>Materials aspects:</u></p> <p>The predicate device has a needle that is made of stainless steel and a body and a cap that are made of plastic materials such as polyethylene (PE). The stainless steel material is bio-compatible and has Elastic Modulus of roughly 200 GPa.</p> <p>The PLANCET has a needle that is made of high performance and bio-compatible plastic material and a body and a cap that are made of plastic materials such as polyethylene (PE). The high performance and bio-compatible plastic material has Elastic Modulus of roughly 3.5 GPa. These needles have sufficient strength for the use of pricking fingers and palms.</p>
Non-Clinical Performance Data	<p><u>Bench tests:</u></p> <p>The durability and strength of the plastic needles were tested in a series of penetration tests using the PLANCET blood lancets loaded in a spring-operated lancing device and a 0.4mm-thick polyurethane (PU) film. Our data show that the PLANCET blood lancets are able to penetrate the PU film repeatedly without damage to the needle tip or body.</p> <p><u>Focus group survey:</u></p> <p>To test the performance (pain level and blood volume) of the PLANCET blood lancets in actual use, a focus group of 18 people was established to conduct a blind study involving a predicate device and the PLANCET. The results showed that the pain level and the blood volume for carrying out a glucose test are comparable to the predicate device. All PLANCET blood lancets were inspected under magnification, and all PLANCET blood lancets remained intact.</p> <p>Our study shows that the PLANCET blood lancets when used with a spring-operated lancing device have comparable functionality performance compared to the predicate device. In particular, the PLANCET blood lancets can penetrate repeatedly (4 times) a thick and hard PU film without damage, ruling out the possibility that they will break and remain in the skin. Our study also shows that PLANCET blood lancets when used with a spring-operated lancing device can obtain sufficient blood for carrying out a glucose test.</p>
Conclusions	<p>Drawing conclusions from our non-clinical data, the PLANCET blood lancets are substantially similar to the predicate device in terms of performance and are safe and effective for the intended use.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUL 13 2012

Re: K113513

Trade/Device Name: PLANCET Blood Lancet
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: I
Product Code: FMK
Dated: June 14, 2012
Received: June 18, 2012

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

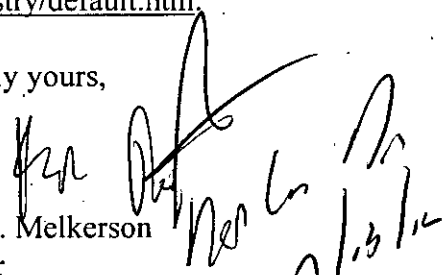
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K113513

Device Name: PLANCET Blood Lancet

Indications for Use:

The PLANCET blood lancet is a puncture device to obtain micro-litre capillary whole blood samples from finger tips or palm or alternate body sites. The PLANCET blood lancet is normally loaded in a spring-operated lancing device for rapid puncture of skin.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Dyke for AnXm
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113513